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DE RUEHKV #2865/01 3271300

ZNR UUUUU ZZH

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FM AMEMBASSY KYIV

TO RUEHC/SECSTATE WASHDC PRIORITY 4392

INFO RUEAWJA/DEPT OF JUSTICE WASHDC

RUCPDOC/USDOC WASHDC

RUCNCIS/CIS COLLECTIVE

UNCLAS SECTION 01 OF 02 KYIV 002865

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E.O. 12958: DECL: N/A

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SUBJECT: UKRAINE: IPR ENFORCEMENT COOPERATION GROUP
DISCUSSES PHARMACEUTICAL INDUSTRY ISSUES

REFS: A) KYIV 1450 and previous

B) 2006 KYIV 4304

¶1. Summary: GOU, Embassy and industry representatives discussed IPR issues of importance to pharmaceutical producers at a November 21 Enforcement Cooperation Group (ECG) meeting. The Ambassador emphasized the importance of IPR enforcement generally, and for the pharmaceutical industry specifically. GOU officials argued that recent legislative and regulatory changes made as part of WTO accession marked major progress. Industry expressed dissatisfaction that the GOU had not fully taken its comments on previous draft regulations into account. The GOU pledged to work to improve the transparency of the drug approval process, and offered to expand its consultations with industry reps. Econoff urged the GOU to properly notify pharmaceutical companies of new market approval applications; the GOU said it was working on the problem and had only the day before resumed posting applications on the internet. The meeting's tone was constructive, and it helped lay the groundwork for improved cooperation between the GOU and the pharmaceutical industry. End Summary.

¶2. On November 21 Ukraine's State Department of Intellectual Property (SDIP) hosted the sixth meeting of the IPR Enforcement Cooperation Group (ECG), with participation of numerous industry representatives. (Note: See Ref A for previous ECG meetings. End Note.) The meeting focused exclusively on IPR issues of importance to the pharmaceutical industry. The Ambassador represented the Embassy and emphasized the importance of IPR enforcement for Ukraine in meeting international and European standards. The Ambassador noted the particular importance of protecting IP rights for the pharmaceutical industry, and encouraged the GOU to cooperate closely with industry.

¶3. The following is a list of key participants:

GOU

Mykola Paladiy - Chairman, SDIP

Volodymyr Zharov - 1st Deputy Chairman, SDIP

Olga Baula - 1st Deputy Chairwoman, State Pharmacological Center

Ludmila Plyuto - Ukrainian Institute of Industrial Property (UkrPatent)

Oleg Gaschytskiy - State Customs Service

Vadim Vnukov - Security Service of Ukraine

Industry

Igor Mozolevich	- Delta Medical
Tatiana Avdeenko	- Eli Lilly
Irina Kukovskaya-Rud	- GlaxoSmithKline
Mikhail Aristov	- Boehringer Ingelheim
Irina Kirichenko	- Law Firm "Ilyashev and Partners"
Ludmila Lushpenko	- Servier
Yuliya Kobuk	- American Chamber of Commerce

(Note: Yuriy Savko, Director of the Association of Pharmaceutical Research and Development (APRaD), industry's lead lobbying group in Ukraine, was unable to attend. Mozolevich represented APRaD on his behalf. End Note.)

WTO-Related Amendments Mark Major Progress...

¶4. Paladiy and Zharov said that the November 2006 amendments to the Law "On Medical Drugs" providing pharmaceutical producers with a five-year period of data exclusivity (ref B) marked a major step forward for IPR protection in Ukraine. Baula, whose State Pharmacological Center handles market approvals for medical drugs, seconded that the corresponding implementing regulations -- Cabinet of Ministers Resolution No. 503 (dated 03/21/07) and Ministry of Health Order No. 426 (dated 10/05/07) -- had clarified regulatory procedures. Baula said that regulations now required all market approval applications to include copies of patent licenses, and that any applications without the necessary documentation were rejected. She said that the State Pharmacological Center's Qualification Council met every Friday to review market approval decisions, and that over 20 percent of applications were in fact rejected.

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... But Industry Concerns not Fully Taken into Account

¶5. Econoff congratulated the GOU on the significant progress, but cautioned that current procedures likely needed additional improvement. Mozolevich asked why industry's proposals on the draft regulatory amendments, sent twice to the GOU by APRaD and the American Chamber of Commerce, were not reflected in the final version of the amendments. (Note: Econoff had participated in meetings of the American Chamber of Commerce's Health Care Committee, during which industry worked out detailed proposals on the draft regulations. End Note.) Baula questioned whether the Ministry had ever actually received their proposals, incensing the industry reps.

¶6. Paladiy stepped in and encouraged industry to send a copy of all such correspondence to SDIP, so that he could ensure it received the attention of the proper GOU agency. Baula subsequently pledged to work with industry to improve the "transparency and openness" of the drug approval process. She noted that the Ministry of Health was willing to introduce additional amendments to regulatory acts, as needed. Econoff noted that, despite a past failure to communicate, the potential for cooperation now seemed ripe -- the GOU was expressing an interest in improving its regulatory procedures, and industry was ready with specific suggestions. Paladiy proposed that Baula and industry reps schedule a follow-on meeting to discuss industry's proposals in detail.

¶7. Paladiy also encouraged industry to comment on a draft Law "On Confidential Information" currently being developed by SDIP. Baula added that the Ministry of Health was drafting a law meant to eliminate any conflicts of interest in the market approval process (i.e. domestic, generic producers playing a role in application decisions), and welcomed industry comment on the draft.

GOU Fixing Notification Problem

¶18. Econoff emphasized the importance of informing major pharmaceutical producers when another company tried to register a drug similar to one already on the market.

(Note: In June, the State Pharmacological Center abruptly stopped posting notifications of registration applications on its website. End Note.) Zharov confirmed that the GOU had promised to address this problem during bilateral consultations held on the margins of October's WTO Working Party Meeting.

¶19. Baula informed participants that the State Pharmacological Center had resumed posting new market approval applications on its website as of November 10 (i.e. the day before the ECG), blaming the temporary change in practice on "technical issues." Mozolevich and Lushpenko asked if industry would be able to access records from the five-month period when the website posting was halted. Baula said yes, but then asked that APRaD send a formal request in order to aid the process.

Comment: First Step towards Better Cooperation?

¶10. Except for frustration over past communication difficulties, the tone of the meeting was overwhelmingly constructive. Baula stayed after the meeting and spoke privately with individual industry reps for over 30 minutes, at one point telling them, "We're all on the same side." Following the meeting, Mozolevich confirmed that APRaD and the American Chamber of Commerce will provide fresh comments on Ministry of Health Order No. 426 to the Ministry, and to Baula personally. Post believes there is goodwill from the GOU and is optimistic that this meeting will mark the beginning of improved cooperation between the GOU and the pharmaceutical industry.

TAYLOR